



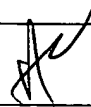
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,760	11/10/2003	Troy Livingston	79611 (1273)	4281
22242	7590	12/01/2004	EXAMINER	
FITCH EVEN TABIN AND FLANNERY 120 SOUTH LA SALLE STREET SUITE 1600 CHICAGO, IL 60603-3406			SONG, HOON K	
			ART UNIT	PAPER NUMBER
			2882	

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/705,760	Applicant(s) LIVINGSTON, TROY	
	Examiner Hoon Song	Art Unit 2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20,27-34 and 40-53 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-26,35-39 and 41-48 is/are allowed.
- 6) ☒ Claim(s) 1,7,8,20,27-29,31,40,49-51 and 53 is/are rejected.
- 7) ☒ Claim(s) 2-6,9-19,30,32-34 and 52 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Objections

Claims 1-3, 5 and 7-8 are objected to because of the following informalities:

In claim 1 on line 11, "the imaging area" lack proper antecedent basis.

In claim 2 on line 3, "a paddle" should read --the paddle--.

In claim 3 on line 5, "it" should read --paddle--; on line 6, "the tilt angle" lacks proper antecedent basis.

In claim 5 on line 9, "the support" lacks proper antecedent basis.

In claim 7 on line 22, "it" should read --the compressed posterior tissue--; on line 23, "the imaging area" lacks proper antecedent basis.

In claim 8 on line 5, "the flexed section" lacks proper antecedent basis.

There are similar informalities are exist throughout the claims.

Appropriate correction for all claims is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-8, 27-29, 49-51 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Niklason et al. (US 5506877).

Regarding claims 1, 7-8, 27-29, 49-51 and 53, Niklason teaches a method of X-ray mammography imaging of a breast having posterior tissue (36a) located at the chest

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wall and a middle and anterior tissue (36b) compressed between a paddle (48) and bucky (34) assembly on opposite sides of the breast, the method comprising:

displacing the paddle (48) and bucky (34) assembly relative to one another in the vertical direction to compress the posterior breast tissue (36a) at the chest wall in the vertical direction only without pushing posterior tissue at the chest wall away from the chest wall or into the chest wall and from the imaging area (column 6 line 1-5);

stopping this vertical displacement prior to compressing the anterior and middle breast portions sufficiently for imaging and in order to lessen the patient's discomfort with further stretching of the posterior skin of the breast at a chest wall of the patient (after the initial desired compression, column 6 line 6);

subsequently, in time, using an inclined surface on the paddle (figure 4) or bucky to compress the middle and anterior breast tissue with a second force which is at an angle (θ) to the first vertical force (I) and which has a horizontal force (II) component which is lesser than the first vertical force (horizontal vector force of II) to prevent the anterior or middle breast tissue from pushing the posterior breast tissue toward the chest wall and from the imaging area (column 6 line 7-11); and

imaging the compressed posterior, middle and anterior breast tissue.

Regarding claim 7, Niklason teaches a method of compressing a breast having posterior, middle and anterior tissue between a paddle and a bucky assembly for mammographic imaging of the breast, the method comprising:

providing a paddle (48) with a compression surface at the upper side of the breast and a bucky (34) having a compression surface at the bottom side of the breast (36);

one of said bucky and paddle surfaces having an inclined compression surface (figure 4);

moving the opposed surfaces relative to one another to compress the posterior portion (36a) of the breast (36) adjacent the chest wall (50) between the compression surfaces with a first vertically directed force (I) to force the posterior breast surface to prevent a substantial shifting of the breast tissue in a horizontal direction toward or from the chest wall (column 6 line 1-5);

compressing the middle and anterior portions of the breast with a second force (II) from the inclined compression surface (48) to compress the anterior (36b) and middle breast tissue (column 6 line 10-12);

the compressed posterior tissue (36a) receiving a horizontally directed force (I) component urging it to move horizontally toward the chest wall (50) and from the imaging area; and

the first force holding the vertically compressed tissue (36a) against the horizontal displacement from the imaging area adjacent the chest wall by the horizontally directed component provided by the inclined compression surface (contoured compression).

Regarding claim 8, Niklason teaches providing an x-ray transparent paddle having a rigid flat section with the second opposed surface and a flexed section (48a)

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with the flexed section and using the inclined compression surface to compress the middle and anterior breast tissues.

Regarding claim 27, Niklason teaches an apparatus for X-ray mammography imaging of a breast having posterior tissue located at the chest wall and a middle and anterior tissue (figure 1) without obstructing the imaging of the breast comprising:

- an X-ray source (40) for applying x-rays to image the breast;

- a paddle (48) located between the x-ray source (40) and the breast (36);

- a compressing surface on the paddle being transparent to x-rays without an occluding hinge or portion of the paddle in the mammography image of the breast (figure 3);

- a bucky assembly (34) on a side of the breast opposite the paddle (46) and having a compression surface engaging the breast (36);

- a drive (62) for shifting the paddle compressive surface and bucky compression surface relative to one another to compress the breast therebetween (figure 3);

- said compressive surfaces compressing the posterior breast tissue (36a) adjacent the chest wall (50) with vertically directed force only without pushing the posterior breast tissue away from the chest wall (figure 3) and to compress this posterior breast tissue sufficiently to lessen any subsequent pushing of breast tissue toward the chest wall (50); and

- an inclined (figure 4) compressive surface portion on one of the compressive surfaces for subsequently, in time, applying a second compression force (II) to compress the middle and anterior breast tissue with a second force (II) which is at an

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angle to the first force (I) and which has a horizontal component lesser than the first vertical force to limit pushing of posterior breast tissue toward the chest wall.

Regarding claim 28, Niklason teaches the paddle(48) having a first horizontal portion (48c) projecting outwardly from the chest wall (50) to apply the first compressive force at the posterior breast; and

an inclined portion (48a) on the paddle joined to an end of the first portion (48c) of the paddle at a location substantially outwardly of the chest wall (50) to apply the second compressive force (II) to the middle and anterior portion of the breast.

Regarding claim 29, Niklason teaches an X-ray transparent hinge portion on the paddle joining the chest wall projecting portion (50) and the inclined portion (48a) for hinging movement of the inclined portion relative to the projecting portion (figure 8a).

Regarding claim 49, Niklason teaches an adjustable paddle for use in a mammography machine having different modes of operation, the paddle (48) comprising:

a posterior portion (48c) for engaging and compressing a posterior portion of the breast;

a biased inclined portion (48a) biased downwardly by a predetermined force from an aligned position in which the inclined portion is aligned with the posterior portion and is biased to an inclined position in which the inclined portion is inclined to the posterior portion (figure 8a);

a releasable lock (58) to lock the inclined portion in an inclined position for a tilt mode compression or in the aligned position during an aligned compression operation (column 7 line 46-51); and

the releasable lock being released to allow the biasing force to push the inclined portion against the middle and anterior breast portions to compress the breast (figure 4).

Regarding claim 50, Niklason teaches the paddle comprises a curved hinge portion between the posterior paddle portion and the paddle inclined portion providing the biasing force (figure 4).

Regarding claim 51, Niklason teaches a paddle for use in a mammographic machine and for compressing anterior, middle and posterior breast tissue comprising:

a first posterior section (48c) having a surface for compressing the posterior breast tissue;

a flexed section (48c) biased to move to an inclined position against the middle and anterior breast tissue to compress the same; and

an X-ray transparent hinge section (52, figure 7) on the paddle between the posterior section (48c) and the flexed section for hinging the sections together, the hinge section extending over the breast and allowing X-rays to pass therethrough without causing a shadow on the X-ray image of the breast (figure 7 and 8).

Regarding claim 53, Niklason teaches the paddle has plastic posterior and flexed sections:

the hinge section being a living hinge formed of the same plastic as the posterior and flexed sections.

Claim 40 is rejected under 35 U.S.C. 102(b) as being anticipated by Virta et al. (US 5050197).

Regarding claim 40, Virta teaches an X-ray mammography machine including a bucky (7) and a compression paddle (6) wherein the bucky (7) and compression paddle (6) are movable relative to one another, and wherein said bucky (7) is tiltable (rotational movement of the C-arm with the bucky) to provide an extended area (side of breast) of breast compression.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niklason in view of Barbarisi (US 4943986).

Regarding claims 20 and 31, Niklason fails to teach providing an upper cover portion on the bucky assembly with an inclined section surface.

Barbarisi teaches providing an upper cover portion on the bucky assembly with an inclined section surface (figure 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to adapt the mammography system of Niklason with the inclined section surface as taught by Barbarisi, since the inclined section surface of Barbarisi would provide improved result of compressing breast than flat surface.

Allowable Subject Matter

Claims 21-26, 35-39 and 41-48 are allowed over prior art.

Claims 2-4, 5-6, 9-14, 15-19, 30, 32-34 and 52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claims 5-6, 11-13, 21, 24 and 26, the prior art fails to teach a method of improving compression of the middle and interior breast tissue in a mammography system by tilting (pivoting) of a bucky assembly toward a paddle as claimed in claims 5, 11, 21, 24 and 26.

Regarding claims 32-35, 39, the prior art fails to teach a bucky for use with an x-ray mammography wherein the bucky is controllably tiltable in relation to a compression paddle as claimed in independent claims 32-35 and 39.

Regarding claims 2-4, 8-10, 14, 15-17, 19, 30, 41-49 and 52, the prior art fails to teach a breast compression paddle for use with an x-ray machine having a portion with flexible section extending from a fixed section for compression of the breast as claimed in 2, 3, 9, 14, 30, 41, 45, 49 and 52


Regarding claim 18, the prior art fails to teach that the first compression force is in the range of 25 to 40 pounds and the subsequent, second compression force is in the range of about 1- to 15 pounds as claimed in dependent claim 18.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hoon Song whose telephone number is (571) 272-2494. The examiner can normally be reached on 8:30 AM - 5 PM, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward Glick can be reached on (571) 272 - 2490. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


DAVID V. BRUCE
PRIMARY EXAMINER

HKS

11/27/04
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